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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,780	08/18/2000	Jacques Dumas	BAYER8C1	7350

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EXAMINER

ROBINSON, BINTA M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/06/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/640,780

Applicant(s)

DUMAS ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 10, 14, 17-42, 44 and 47-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 11-13, 15, 16, 43 and 46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

The examiner notes that the applicant traverses the restriction requirement at paper no. 10 asserting under MPEP §803 that "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." The examiner, however, has not required election/restriction under MPEP 803.02. The examiner has restricted the application to a single, independent invention. If restriction was not applied, there would be a serious burden, because heteroaryl, or heterocyclic rings are classified in multiple classes of 546, 548, and 549. The applicant has asserted that only one subclass for searching the methods of group I has been cited and not one separate class of search for the methods of Group II has been cited. The examiner has noted that Groups I and Group II would be classified in multiple classes and subclasses.

The applicant asserts that the examination of the entire claimed subject matter would not be a serious burden upon the examiner because the claimed methods allegedly have a common utility and the compounds used in the claimed methods are ureas having a 5-membered heterocyclic group on one side of the urea functionality and an aryl or heteroaryl group on the opposite side of the urea functionality. However the applicant is claiming both a product and a method of using the product. The inventions of a product and method of using a product can be shown to be distinct if the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, these compounds can be used to treat peripheral hyperalgesia. See compound, 2-Thiophenecarboxamide, N-(5-nitro-2-thiazolyl)- in

Art Unit: 1625

Yaksh et. al. (see WO 9709973), which is different from the claimed method of treating cancerous cell growth mediated by raf kinase. Applicants have failed to point out the supposed errors in the restriction requirement in order to be entitled to a request for reconsideration. Applicants must point out supposed errors. Failure to do so is acquiescence. See MPEP 81803a.

The Markush objection of claims 1-4, 9, 11-16, 43, and 46 and the 112, second paragraph rejections at paper no. 10 of claims 1-4, 9, and 11-16 have been withdrawn in light of applicant's remarks at paper no. 10.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9, 11-13, 15-16, 43 and 46 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 9. because the specification, does not provide enablement for B, R₅ and R_{5'}, and Z_{n1} equal to all heteroaryl groups, all substituted and unsubstituted C4-C23-alkheteroaryl groups, all C3-C13 heteroaryl groups, or Ar equal to all possible 5-10 member aromatic structures containing 0 to 4 members of the group consisting of nitrogen, oxygen, and sulfur which is unsubstituted or substituted by halogen up to per-halosubstitution and optionally substituted by Zn1, wherein n1 is 0 to 3 and each Z is independently selected from the group consisting of the groups claimed in claim 1, or R1 equal to all C1-C13 heteroaryl groups, R2 equal to

Art Unit: 1625

all C4-C23 alkheteroaryl groups, or C4-C23 alkheteroaryl groups, R3 and R3' equal to C4-23 alkheteroaryl groups C3-C13 heteroaryl groups, C4-C23 alkheteryl groups, or R1 and Rc coming together to form all possible 5- or 6- membered heteroaryl rings with 0 to 2 members selected from O, N and S. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, B encompasses a whole Markush

Art Unit: 1625

grouping of moieties other than the substituted phenyl, pyridyl, or thiophenyl rings claimed. In terms of the fifth Wands and sixth Wands factor, the level of predictability in the art and the amount of direction provided by the inventor are low. The effect of the compounds exemplified in the specification on raf kinase activity ranges from IC_{50} s 1 to 10. The results of the cellular assay and the in vivo assay of the inhibitory effect of the compounds on tumors were not displayed for each of the specific compounds exemplified. Additionally, the applicant does not provide working examples or test data for the compounds where B can equal moieties other than substitute phenyl or pyridyl, or thiophenyl rings-exemplified.

What cancers, cell lines, what specific tests were performed to show that cancerous cell growth has been reduced in scope? In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

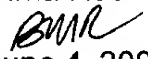
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers

Art Unit: 1625

for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson


June 4, 2002



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600